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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/508,340

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Yasuhiro Koga

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7590

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ALEXANDRIA, VA 22314-1176

EXAMINER

KIM, TAEYOON

ART UNIT

PAPER NUMBER

1651

MAIL DATE

DELIVERY MODE

11/13/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/508,340

**Applicant(s)**

KOGA, YASUHIRO

**Examiner**

TAEYOON KIM

**Art Unit**

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 July 2008.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 2-4, 7, 8, 10-12 and 16 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 2-4, 7, 8, 10-12 and 16 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO/S508)  
Paper No(s)/Mail Date \_\_\_\_\_  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 2-4, 7, 8, 10-12 and 16 are pending.

#### ***Response to Amendment***

Applicant's amendment and response filed on 7/28/2008 has been received and entered into the case.

Claims 1, 5, 6, 9 and 13-15 are canceled, claim 16 is newly added, and claims 2-4, 7, 8, 10-12 and 16 are pending and have been considered on the merits. All arguments have been fully considered.

The claim rejection under 35 U.S.C. §112, 2<sup>nd</sup> para., has been withdrawn due to the amendment.

The claim rejection under 35 U.S.C. §112, 1<sup>st</sup> para., has been withdrawn based on the indication of public availability in the amendment.

The claim rejection under 35 U.S.C. §101 to claims 6 and 9 has been withdrawn due to the amendment.

The claim rejection under 35 U.S.C. §102(b) and 103(a) based on Katoh et al. have been withdrawn due to the amendment.

Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 2-4, 7, 8 and 16 are rejected under 35 U.S.C. 102(a) as being anticipated by Katoh et al. (WO/2002/16554; see attached machine translated version).

Katoh et al. teach a probiotics or composition containing *Lactobacillus Salivarius* WB1004 (FERM BP-7791) or *Lactobacillus Salivarius* WB21 (FERM BP-7792) (see claims and Table 2), and the use of the probiotics for prevention of an alimentary canal disease including diseases in oral cavity and periodontosis (see Example 4, p.16 of translated version). Katoh et al. also teach dried bacillus in Work example 1 (p.18).

Although it is acknowledged that the specification discloses differences between various strains of *Lactobacillus Salivarius* (e.g. Table 1 of the specification), and might show unique properties of the claimed strain of FERM BP-7974 compared to the limited number of other strains, it has not been established whether the claimed strain is novel and clearly different from those taught by Katoh et al. Therefore, the examiner takes a position that the strain of Katoh et al. is the same as the claimed strain.

The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' strain differs, and if so to what extent, from the strain discussed in Katoh et al. Accordingly, it has been established that the prior art strain, which (has the same genus and species classification and share the property of being able to produce lactic acid), demonstrates a reasonable probability that it is either identical or sufficiently similar to the claimed strain that whatever differences exist are not patentably significant. Therefore, the burden of establishing novelty or unobviousness by objective evidence is shifted to applicants.

Merely because a characteristic of a known strain is not disclosed in a reference does not make the known strain patentable. The new strain possesses inherent characteristics which might not be displayed in the tests used the reference. Clear evidence that the strain of the cited prior art do not possess a critical characteristic that is possessed by the claimed strain, would advance prosecution and might permit allowance of claims to applicants' strain.

Thus, the reference anticipates the claimed subject matter.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Katoh et al. (supra) in view of Klueppel et al. (US 4,726,943).

Katoh et al. teach a composition comprising *Lactobacillus salivarius* strain for periodontosis and other oral cavity diseases.

Katoh et al. do not teach additional component/substance selected from sugar alcohol or oligosaccharides.

Klueppel et al. teach the use of polyol (sugar alcohol) such as erythritol for anti-caries composition (see col. 1, line 66 through col. 2, line 19, especially, line 14 of col. 2).

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to combine erythritol of Klueppel et al. with the composition of *Lactobacillus Salivarius* of Katoh et al.

M.P.E.P. §2144.06 states "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be prima facie obvious.). See also *In re Crockett*, 279 F.2d 274, 126 USPQ 186 (CCPA 1960) (Claims directed to a method and material for treating cast iron using a mixture comprising calcium carbide and magnesium oxide were held unpatentable over prior art disclosures that the aforementioned components individually promote the formation of a nodular structure in cast iron.); and *Ex parte Quadranti*, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992) (mixture of two known herbicides held prima facie obvious).

Since the purpose of *Lactobacillus salivarius* of Katoh et al. and erythritol of Klueppel et al. is as anti-caries or treatment of caries, these two components are for the same intended use and thus, it is obvious to combine these two components in a composition for anti-caries agent.

Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill at the time the invention was made.

***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TAEYOON KIM whose telephone number is (571)272-9041. The examiner can normally be reached on 8:00 am - 4:00 pm ET (Mon-Thu).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford/  
Primary Examiner, Art Unit 1651

Taeyoon Kim